

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

VIVEVE, INC., §
§
Plaintiff, §
§
v. §
§
THERMIGEN, LLC; §
THERMIAESTHETICS, LLC; AND RED §
ALINSOD, M.D., §
§
Defendants. §

CASE NO. 2:16-CV-1189-JRG

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Red Alinsod, M.D.’s Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(1), 12(b)(2), and 35 U.S.C. § 287(c). (Dkt. No. 14.) On February 22, 2017, the Court held a hearing at which the parties presented oral argument on said motion. After considering the briefing and argument of the parties, and for the reasons set forth below, the Court finds that Defendants’ motion should be and is **DENIED**.

I. BACKGROUND

On October 21, 2016, Plaintiff Viveve, Inc. (“Plaintiff” or “Viveve”) filed its original complaint for infringement of U.S. Patent No. 8,961,511 (the “’511 patent”) against Defendants Thermigen, LLC; ThermiAesthetics, LLC; and Dr. Red Alinsod, M.D. (*See* Dkt. No. 1.) Viveve alleges that Defendants produce and market a vaginal reconstruction procedure under the name “ThermiVa,” which purportedly infringes the ’511 patent. (Dkt. No. 1 at ¶ 34.) According to Viveve, the ThermiVa procedure uses a radio frequency, thermistor tip to control heat delivery to specific genital tissues to tighten the target zone. (*Id.*) Most relevant to the present motion, Viveve alleges that Dr. Alinsod, in his individual capacity, both (1) directly infringes the ’511 patent by

performing the procedures claimed therein and (2) induces others to infringe the '511 patent. (Dkt. No. 1 at ¶¶ 38–39, 44–50.)

Dr. Alinsod is a practicing urogynecologist who is licensed in the state of California. (Dkt. No. 14 at 4.) Viveve alleges that Dr. Alinsod is “the face of ThermoVa,” and that his commercial development efforts aimed at selling and marketing the ThermoVa procedure constitute the basis for his alleged infringing conduct. (Dkt. No. 22.) In support of these allegations, Viveve asserts that Dr. Alinsod is an executive of ThermoAesthetics (one of the other named Defendants), that he is Charman of the Women’s Health Clinical Advisory Board at ThermoAesthetics, and that he is the owner of the ThermoVa.org website. (Dkt. No. 1 at 15, 20.)

On December 19, 2016, Dr. Alinsod filed his motion to dismiss pursuant to 12(b)(1), 12(b)(6), and 35 U.S.C. § 287(c). (Dkt. No. 14.) Dr. Alinsod argues that 35 U.S.C. § 287(c), the so-called “Physician’s Immunity Statute,” either deprives the Court of jurisdiction over a claim against him in his personal capacity or provides a defense rendering Viveve’s claims against him implausible and thus worthy of dismissal under Rule 12(b)(6).¹

II. LEGAL STANDARD

A. Rule 12(b)(6)

Rule 8(a) of the Federal Rules of Civil Procedure, which governs pleadings in patent infringement cases, provides that a claim must contain “a short and plain statement of the claim

¹ Although Dr. Alinsod’s motion was filed as both a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) and a motion to dismiss for failure to state a claim under Rule 12(b)(6), the Court will consider his motion under Rule 12(b)(6) alone. Given that the Court concludes Dr. Alinsod cannot satisfy the requirements of § 287(c)(1), the question of whether the provision is jurisdictional is not squarely before the Court. *See Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811, 819 n.2 (S.D. Tex. 2008) (“Because the movants do not satisfy the requirements for immunity under section 287(c), the question of whether section 287(c) is jurisdictional is not addressed”). Thus, the Court need not decide whether § 287(c) is jurisdictional. Accordingly, for purposes of simplicity, and in light of Supreme Court precedent regarding the nonjurisdictional/jurisdictional distinction, the Court will address the provision in the context of Rule 12(b)(6). *See, e.g., Arbaugh v. Y&H Corp.* 546 U.S. 500, 515–516 (2006) (noting that when Congress does not explicitly rank a statutory limit as jurisdictional, courts should treat the limitation as nonjurisdictional in nature); *see also United States v. Kwai Fun Wong*, 135 S. Ct. 1625, 1632 (2015) (same).

showing that the pleader is entitled to relief.” When considering a motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court must assume that all well-pleaded facts are true and view those facts in the light most favorable to the plaintiff. *Bowlby v. City of Aberdeen*, 681 F.3d 215, 218 (5th Cir. 2012). The court may consider “the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint.” *Lone Star Fund V (U.S.) L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010). The court must then decide whether those facts state a claim for relief that is plausible on its face. *Bowlby*, 681 F.3d at 217. “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). As the Supreme Court noted, the plausibility requirement is not akin to a “probability requirement at the pleading stage; it simply calls for enough fact[s] to raise a reasonable expectation that discovery will reveal” that the defendant is liable for the alleged misconduct. *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 556 (2007).

B. Section 287(c)(1): The Physician’s Immunity Statute

Section 287(c) provides medical practitioners and related entities with a defense to infringement. *See Lamson v. U.S.*, 117 Fed. Cl. 755, 762–63 (2014). Section 287(c)(1) of the Patent Act states: “With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.” 35 U.S.C. § 287(c)(1). The term “medical practitioner” is defined in § 287(c)(2)(B) as “any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the

performance of the medical activity.” *Id.* at 287(c)(2)(B). The statute also defines the term “medical activity” as “the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.” *Id.* at 287(c)(2)(A).

C. Section 287(c)(3): Exceptions to the Physician’s Immunity Statute

Even if the elements of the defense provided in § 287(c)(1) are met, that provision does not apply to:

the activities of any person, or employee or agent of such person . . . who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services . . . where such activities are:

- (A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services . . . and
- (B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

35 U.S.C. § 287(c)(3).

III. ANALYSIS

The Court finds that Viveve has satisfactorily stated claims for both direct and indirect infringement against Dr. Alinsod.

A. Direct Infringement

In its complaint, Viveve alleges that Dr. Alinsod has infringed the ’511 patent by “using, providing, selling, and/or offering for sale services that utilize the patented methods.” (*Id.* at ¶ 44.) In support of this claim, Viveve points to Dr. Alinsod’s appearance on a daytime television program called “The Doctors” (which the Court discusses in detail *infra*) and a study conducted by Dr. Alinsod and its accompanying article titled “Temperature Controlled Radiofrequency for Vulvovaginal Laxity.” (*Id.* at ¶¶ 38, 46–48; Dkt. No. 1-2.) Standing alone, Viveve’s complaint

adequately states a claim for direct infringement that clears the plausibility requirement imposed by Rule 12(b)(6).

The real issue in this case, however, is whether Dr. Alinsod's statutory defense under § 287(c) renders Viveve's claims implausible, and thus worthy of dismissal. As discussed above, § 287(c)(1) provides that the civil remedy provisions of the Patent Act shall not apply to "medical practitioners" and "related healthcare entit[ies]" performing "medical activities" which would otherwise constitute infringement. *See* 35 U.S.C. § 287(c)(1). Dr. Alinsod argues that Viveve has failed to state a claim for direct infringement because it has alleged that he is a licensed medical doctor who has allegedly infringed the '511 patent by performing a medical activity (i.e., the method claimed in the '511 patent) on patients. (Dkt. No. 14 at 5–6.) According to Dr. Alinsod, the Physician's Immunity Statute exempts him from liability for such conduct. (*Id.*) Viveve counters by arguing that even if the defense provided in § 287(c)(1) applies, the exception contained in § 287(c)(3) renders (c)(1) inapplicable. (Dkt. No. 22 at 4.) In support of this argument, Viveve asserts that Dr. Alinsod is engaged in the commercial development of the ThermoVa device and procedure, that his accused conduct is directly related to the commercial development of ThermoVa, and that these activities are regulated under the Federal Food, Drug and Cosmetic Act. (*Id.* at 4–14.)

Initially, the Court finds it important to clarify the scope of the conduct at issue. In the context of direct infringement, Dr. Alinsod's allegedly infringing conduct falls into two categories: (1) performance of the process in relation to promotional activities directly related to the commercial development and sale of the ThermoVa device and procedure, and (2) performance of the process on his patients in his private medical practice. Here, Viveve has only accused conduct falling into the former category, and has explicitly disclaimed conduct falling into the latter. (*See*

Dkt. No. 1 at ¶¶ 38, 44–48; Dkt. No. 22 at 1.) Accordingly, the scope of Dr. Alinsod’s conduct at issue is limited to his activities related to the commercial development and sale of the ThermoVa device and procedure. With this clarification regarding the scope of the conduct at issue providing the relevant background, the Court proceeds to analyze the defense provided by § 287(c)(1) and the carve out under § 287(c)(3).

There are essentially two substantive elements to § 287(c)(1): (1) that the defendant be a “medical practitioner,” as defined in the statute; (2) who is accused of infringing based upon the performance of a “medical activity,” as defined in the statute. *See* 35 U.S.C. § 287(c)(1). The parties do not appear to dispute the first element. Dr. Alinsod is a urogynecologist licensed by the state of California—he appears to fall squarely within the statutory definition of “medical practitioner,” which includes “any natural person who is licensed by a State to provide . . . medical activity.” *Id.* at 287(c)(2)(B). Whether his accused conduct constitutes the performance of a “medical activity,” however, is a closer call. The statute defines “medical activity,” in relevant part, as “the performance of a medical or surgical procedure on a body.” *Id.* at § 287(c)(2)(B). At first glance, it may not appear as if the types of commercial development activities accused by Viveve constitute “medical activities,” however Dr. Alinsod’s argument to the contrary is not implausible. To illustrate, the Court highlights Dr. Alinsod’s appearance on the popular television program “The Doctors,” in which he both *performs* the method purportedly claimed by the ’511 patent and *markets* the device and procedure, all at the same time. (*See* https://www.youtube.com/watch?v=ywlHI4bL8_4.) Marketing and commercial development activities do not squarely fall within the statutory definition of “medical activities,” however his performance of the procedure would appear to fall within the definition. The intertwining of his

performing medical activities while at the same time actively marketing the product at issue makes this a close call.

Ultimately, however, the Court need not resolve the applicability of § 287(c)(1) in this case. This issue is not dispositive, as the Court concludes that the exception to such immunity contained in § 287(c)(3) applies. As a result, even if the Court found that § 287(c)(1) applied, the exception in § 287(c)(3) would preclude Dr. Alinsod from claiming the defense in (c)(1).

Section 287(c)(3) essentially has two elements. If the medical activities described in (c)(1) are: (1) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter...; and (2) regulated under certain federal statutes, then § 287(c)(1) does not provide a defense. *See* 35 U.S.C. § 287(c)(3). The Court finds that both of these elements are satisfied.

1. Section 287(c)(3)—Element One

In its Complaint and Response to Dr. Alinsod’s motion to dismiss, Viveve both identifies specific activities of Dr. Alinsod’s that it alleges constitute infringement and explains how these activities satisfy the first element of the exception contained in (c)(3). As a “prime example” of his infringing activities, Viveve identifies Dr. Alinsod’s appearance on the daytime television show “The Doctors” on September 28, 2015. (https://www.youtube.com/watch?v=ywlHI4bL8_4.)² During his appearance, Dr. Alinsod explains the benefits of the ThermiVa device and procedure to the show’s hosts and (more importantly) the audience. He even quotes pricing for the procedure (ranging from \$3,500 for a single treatment or \$6,500 for a series of three treatments). (Dkt. No. 22 at 7–8;

² The Court limits its substantive analysis in this Memorandum Opinion to Dr. Alinsod’s appearance on “The Doctors.” While Viveve also alleged other conduct as infringing, the Court need not engage in a tedious analysis of such conduct in light of its conclusion that, at a minimum, Viveve has stated a claim by identifying this particular segment.

https://www.youtube.com/watch?v=ywlHI4bL8_4.) While on the show, Dr. Alinsod also actually performs the procedure (behind medical draping) on a patient and one of the hosts of the show. (*Id.*)

Dr. Alinsod attempts to characterize his appearance on this show as merely informational rather than commercial, stating “[t]he premise of the program is to inform the public about medical procedures and give general medical advice.” (Dkt. No. 25 at 4.) He points to a case from the Southern District of Texas, which held that “providing instructions to a medical caregiver about a patient” or “aiding the treatment of a medical condition” constitutes “medical or surgical procedures” performed “on a body” under the statute. (Dkt. No. 25 at 4); *see Emtel*, 583 F. Supp. 2d at 820, 823. In light of this interpretation, he argues that his appearance on the show constitutes the “exchange of information,” which is “exactly what the legislation intended to preserve.” (Dkt. No. 25 at 5.) The Court disagrees. Even if the Southern District of Texas is correct in its interpretation of the term “medical activity” as it appears in § 287(c)(1), such activity may still be “directly related” to the “commercial development” or “sale” of a machine or manufacture, thus bringing it within the scope of the carve out in (c)(3). Therefore, simply concluding that conduct constitutes “medical activity” does not resolve the issue of whether (c)(3) applies. When focusing on the issue of whether his activity is “directly related” to the “commercial development” or “sale” of a device, the Court is persuaded that Dr. Alinsod’s attempt to characterize his conduct on the television show as a mere effort to facilitate the treatment of patients fails. The Court has observed the footage at issue and concludes that Dr. Alinsod’s appearance on “The Doctors” was overwhelmingly directed to one purpose: product promotion. Seemingly the entire segment is devoted to extolling the virtues of the ThermiVa device and procedure, and is much closer to an advertisement than a medical lecture. Under these facts, the literal requirements of the first element

are satisfied: Dr. Alinsod’s “medical activities” are “directly related” to the “commercial development” or “sale” (i.e., his appearance on “The Doctors”) of a “machine, manufacture, or composition of matter” (i.e., the ThermoVa device). *See* 35 U.S.C. § 287(c)(3).

Dr. Alinsod makes one last argument under this element. He claims that because the ThermoVa “device cannot possibly infringe the ’511 patent . . . especially since the patent does not claim any device at all,” (c)(3) is inapplicable. (Dkt. No. 25 at 6.) The Court disagrees. There is no requirement in the text of § 287(c)(3) which requires that the “machine, manufacture, or composition of matter” at issue infringe the patent in suit. *See* 35 U.S.C. § 287(c)(3). Rather, the only requirement in element one is that the “medical activity” alleged to infringe be “directly related” to the “commercial development” or “sale” of such device. Whether the device allegedly infringes is immaterial. Accordingly, the Court declines Dr. Alinsod’s invitation to read additional requirements into the text of § 287(c)(3).

2. Section 287(c)(3)—Element Two

The second element of § 287(c)(3) requires that the defendant’s activities (i.e., those which constitute the “commercial development” or “sale” of the “machine, manufacture, or composition of matter”) be “regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.” 35 U.S.C. § 287(c)(3)(B). Here, the Court perceives no real dispute. Viveve argues that Dr. Alinsod’s conduct is regulated under the Federal Food Drug, and Cosmetic Act (“FDCA”). (Dkt. No. 22 at 13.) In support thereof, Viveve shows that the ThermoVa product is a “device,” as defined in § 201(h) of the FDCA, and that medical devices are regulated under the FDCA. (*Id.* citing 21 U.S.C. § 321(h); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); FDCA §§ 501, 502.) One of the ways in which a medical device can be approved by the Food and Drug Administration (“FDA”) is through the filing of a section

510(k) notification, which indicates that the device at issue is substantially equivalent to an existing device. *Id.* Here, ThermoGen filed multiple section 510(k) notifications, which were granted by the FDA on August 12, 2016. (See Dkt. No. 22-10.) Finally, Viveve points to provisions of the FDCA which govern the commercial development and sale of medical devices. *See* 21 U.S.C. §§ 360(e), (i), (j). In response to this argument and evidence, Dr. Alinsod does not appear to dispute that his conduct is regulated by the FDCA. (See Dkt. No. 25 at 6.) Rather, he argues that the ThermoVa device cannot infringe the '511 patent because the patent does not claim a device. (*Id.*) Accordingly, the Court finds that Dr. Alinsod's conduct is regulated by the FDCA, and thus satisfies the second element of the exception provided in § 287(c)(3).

B. Induced Infringement

The Court reaches the same conclusion with regard to Viveve's claims for induced infringement—namely, that § 287(c)(1) does not provide a defense. Nonetheless, the Court addresses this claim separately simply for purposes of clarity.

There is really only one difference in the analysis regarding induced infringement as compared to the analysis of direct infringement: the conduct at issue. Unlike direct infringement, the analysis here focuses on Dr. Alinsod's *instruction* to others regarding how to perform the allegedly claimed procedure. To support its allegations of induced infringement, Viveve asserted in its Complaint that Dr. Alinsod has “knowingly taken active steps to encourage and facilitate direct infringement by others, such as third-party medical providers, who use the patented methods.” (Dkt. No. 1 at ¶ 49.) Again, Viveve points to Dr. Alinsod's appearance on “The Doctors” as evidence of his induced infringement, in addition to the study previously mentioned and other materials provided by the defendants. (Dkt. No. 1 at ¶¶ 49–50.)

Ultimately, the Court finds that the distinction in conduct supporting the claim for direct infringement versus the conduct supporting the claim for induced infringement is one without a difference. Dr. Alinsod argues that the instruction to others constitutes “medical activity” under the Southern District of Texas’ decision in *Emtel*. (Dkt. No. 14 at 6–7.) As mentioned above, in *Emtel* the court found that “providing instructions to a medical caregiver about a patient” or “aiding the treatment of a medical condition” constitutes “medical or surgical procedures” performed “on a body” under the statute. *See Emtel*, 583 F. Supp. 2d at 820, 823. While this may be a correct statement of the law, these are different facts. Even if Dr. Alinsod’s “instruction” provided on “The Doctors” constitutes “medical activity,” the Court finds that the exception provided in § 287(c)(3) applies. As the Court has already discussed, Dr. Alinsod’s appearance on television was wholly commercial in nature. This sales pitch satisfies the first element of (c)(3) because it is “directly related” to the “commercial development” or “sale” of a device. Additionally, as discussed above, this conduct appears to be regulated by the FDCA. Accordingly, the exception in § 287(c)(3) applies even if the defense in § 287(c)(1) is triggered.

IV. CONCLUSION

For the reasons stated above, the Court finds that Viveve has stated plausible claims for direct and induced infringement against Dr. Alinsod and that the provisions for physician’s immunity do not apply. Accordingly, Dr. Alinsod’s Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(1), 12(b)(2), and 35 U.S.C. § 287(c) (Dkt. No. 14) is **DENIED**.

So ORDERED and SIGNED this 20th day of April, 2017.


RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE